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In re
Centre International de Recherches Dermatologiques
U.S. Patent No. Re. 34,440
DIFFERIN SOLUTION

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DISMISSAL OF PATENT
TERM EXTENSION
APPLICATION

An application for patent term extension of U.S. Patent Re. 34,440 based upon the human drug product DIFFERIN SOLUTION (adapalene) was filed by Centre International de Recherches Dermatologiques in the Patent and Trademark Office on July 26, 1996. Applications for patent term extension of U.S. Patent Nos. Re. 34,440, 4,717,720, 5,015,758, and 5,212,303 were also filed based upon the regulatory review of the product DIFFERIN Gel (adapalene), and of U.S. Patent Nos. Re. 4,717,720, 5,015,758 and 5,212,303 based upon the regulatory review of the product DIFFERIN Solution (adapalene) on July 26, 1996.

On February 24, 1999, the PTO mailed a Notice of Final Determination in the above-noted application informing applicant that the patent qualifies for patent term extension but for the fact that only one patent may be extended for the same regulatory review period for a product. See 35 U.S.C. § 156(c)(4). Applicant was given a period of one-month to elect the patent for which term extension was desired for each regulatory review period.

On March 14, 1999, applicant filed a paper electing to have the term of U.S. Patent No. 4,717,720 extended based upon the regulatory review period of DIFFERIN SOLUTION and a second paper electing to have the term of U.S. Patent No. Re. 34,440 extended based upon the regulatory review period of DIFFERIN GEL. Accordingly, the application for patent term extension of the term of U.S. Patent No. Re. 34,440 based upon DIFFERIN SOLUTION is dismissed under 35 U.S.C. 156(c)(4).

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson, Senior Legal Advisor
Special Program Law Office, Office of the DAC for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
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RE: DIFFERIN SOLUTION
FDA Docket No.: 96E-0362